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TO: Commissioner Christine C. Ferguson and Members of the Public Health Council

THROUGH: Paul Dreyer, Ph.D. Interim Associate Commissioner, Center for Health Quality Assurance and Control

FROM: Grant Carrow, Ph.D., Director
Drug Control Program

DATE: March 30, 2004

RE: Request for Final Promulgation of Amendments to 105 CMR 700.000:
Implementation of M.G.L. c. 94C

Introduction

The purpose of this memorandum is to request the Public Health Council's approval for final promulgation of regulations to authorize administration of epinephrine and nerve agent antidotes by certain certified individuals as well as trained first responders and other non-medical staff utilizing autoinjectors in emergencies involving anaphylaxis or nerve agent release. The proposed regulations would permit:

1. Authorized public employees whose functions include emergency preparedness and response, including first responders, to administer prescribed epinephrine and approved nerve agent antidotes for force protection.
2. Authorized staff in municipal or state funded, operated or licensed programs to administer prescribed epinephrine to individuals served by such programs.
3. Certified EMS First Responders (EFRs) to administer Schedule VI medications to the public.
4. Authorized first responders to administer epinephrine to the public.

A public hearing on the proposed amendments was held on January 28, 2004 and a public comment period was held open until February 6, 2004. The rationale for and approach to the proposed regulations are described in greater detail below. The proposed amendments are in Attachment A.

Rationale

Increasing concern about anaphylaxis, particularly among children and young adults, has placed emphasis on the need for improved emergency response mechanisms for programs operated by or overseen by the Commonwealth. Similarly, increasing focus on preparedness for municipal and public agency response to potential bioterrorism incidents has pointed up the need to have mechanisms in place to deliver nerve agent antidotes quickly to emergency workers for force protection.

Department of Youth Services (DYS) officials brought to our attention their concerns that they have experienced both an increased number of clients in their custody with a history of anaphylaxis and an increased incidence of anaphylaxis events. While cases have been managed successfully to date, DHS officials expressed concern that medical and nursing staff are not always readily available to intervene. Moreover, there are no DHS settings within 5 minutes of EMS response time anywhere in the state and several residences are located in rural sites more than 15 minutes from an EMS service.

The proposed amendments would permit first responders to administer epinephrine in a life threatening emergency involving anaphylaxis. First responder agencies have also brought to our attention the need to protect their forces in the event of a bioterrorism event or industrial accident involving organophosphate nerve agents. Should first responders in the course of responding to an incident be exposed to a nerve agent and suffer nerve agent-induced seizures, they may be unable to self-administer antidote. Since antidote must be administered to such individuals within minutes of exposure, waiting for EMS response is not practical.

Thus, emergencies involving anaphylaxis or exposure to nerve agents often require response times that are less than can be provided by EMS services. Potential morbidity and mortality from such incidents could be reduced if those first on scene were able to administer epinephrine to individuals experiencing anaphylaxis or antidotes to partners and colleagues exposed to nerve agents. The regulations proposed here expand the capacity of staff in public agencies, including first responders, to respond to such emergencies in the time prior to EMS response.

Epinephrine, the major treatment for anaphylaxis, and pralidoxime chloride and atropine, the combination antidote to organophosphate nerve agents, are available in dose-metered auto-injectors designed for self-administration. Because these devices do not require measuring or syringes to manipulate, they are simple, easy-to-use, and enable a rapid and accurate dosing of medication, even if the affected person is in protective clothing. Currently, there is no regulatory impediment to self-administration using these devices. Authorized, appropriately trained individuals should likewise be able to safely administer these pharmaceuticals to their partners, colleagues and charges using auto-injector devices. Similarly, appropriately trained first responders should be able to administer epinephrine to individuals experiencing anaphylaxis. The benefits of administering these life-saving pharmaceuticals outweigh any risks of possible inappropriate or unnecessary administration.

Approach

To facilitate emergency preparedness by municipalities and public agencies of the Commonwealth, we propose a new registrant category encompassing municipalities and agencies of the Commonwealth. All municipalities and agencies that wish to authorize certain of their employees or employees of programs that they fund, operate or license to administer

epinephrine or antidotes would register with the Department. A licensed practitioner would be named on the Massachusetts Controlled Substances Registration to assume responsibility for compliance with Department guidelines, including the exercise of medical control over the authorized activities.

The proposed regulations would require that all auto-injectors containing epinephrine or antidotes be administered pursuant to the prescription or order of a practitioner who is duly authorized and registered. In the case of prescribed epinephrine, this requirement would be satisfied by the prescription and any additional instructions from the prescriber. In the case of non-prescribed epinephrine and other antidotes, we expect that standing orders would be used, including the Statewide Treatment Protocols for EMS and EFR personnel and first responders.

The regulations would require medical and drug controls, written protocols and procedures for trainings, retrainings and evaluations and maintenance of records, among other requirements. These requirements would ensure that personnel are able to readily recognize the signs and symptoms of an anaphylactic reaction or nerve agent poisoning and to treat others in a safe, timely and effective manner.

Additional changes to the regulations are necessary to maintain consistency with the changes that the Department has made to its Emergency Medical Services System regulations. This includes authorizing administration of Schedule VI controlled substances by a new category of certified Emergency First Responders (EFRs) and of epinephrine by first responders (police, fire).

Public Hearing and Comment

Verbal testimony was received from one person at the hearing, who was supportive of the intent of the amendments. No written testimony was received.

There was concern expressed in testimony that the programs for first responder administration of epinephrine be voluntary. The proposed amendments permit such programs, but do not mandate them. Local service zones would have the authority to determine whether their first responders should have such a program.

The testifier also suggested that there be training minimums for first responders established by DPH and that first responder services should have to submit plans and progress reports to DPH on their epinephrine programs. The proposed regulations would require training and oversight as well as adherence to any applicable DPH protocols. However, our regulatory approach is to place the responsibility for setting training standards and oversight at the local level, that is, under the medical directors of the first responder services.

Conclusion

Department staff believe that the proposed regulations would reduce morbidity and mortality from exposure to antigens and organophosphate nerve agents. The regulations would permit the establishment of voluntary programs with the appropriate medical and drug controls. For these reasons, we request approval for final promulgation of the amended regulations.

ATTACHMENT A

Proposed Amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C

700.001: Definitions

Delete the following definitions:

~~ALS Attendant means a person employed by an ambulance service licensed to provide Advanced Life Support services in accordance with 105 CMR 170.502, or a person employed by a hospital which provides non-transport pre-hospital Advanced Life Support services, who has met the training requirements of 105 CMR 170.820: *EMT-Intermediate* or 105 CMR 170.840: *EMT-Paramedic* and is certified by the Department in accordance with 105 CMR 170.910. The term ALS attendant shall also include a person who has met the training requirements of 105 CMR 170.810: *EMT-Basic* and is certified according to 105 CMR 170.910, or who is currently certified by another state as an EMT, who is enrolled as a student in a training program at the Intermediate or Paramedic level which has been approved by the Department in accordance with 105 CMR 170.960 and when participating in that training program.~~

~~Pre-Hospital ALS Service means an ambulance service licensed to provide Advanced Life Support in accordance with 105 CMR 170.502 or a hospital unit which provides non-transport pre-hospital Advanced Life Support services.~~

Insert the following definitions:

Ambulance Service means an entity licensed as an ambulance service by the Department in accordance with M.G.L. c. 111C, §6 and 105 CMR 170.000.

EMS First Responder (EFR) means a person certified as an EFR by the Department, in accordance with M.G.L. c. 111C, §9 and 105 CMR 170.000, and authorized to administer controlled substances pursuant to his or her certification and the Statewide Treatment Protocols.

EMS First Response Service (EFR Service) means an entity licensed as an EFR service by the Department in accordance with M.G.L. c. 111C, §6 and 105 CMR 170.000

Emergency Medical Technician (EMT) means a person certified by the Department, pursuant to M.G.L. c. 111C, §9 and 105 CMR 170.000, and authorized to administer controlled substances pursuant to his or her level of certification and the Statewide Treatment Protocols. The term EMT shall include EMT-Basic and the ALS levels of EMT-Intermediate and EMT-Paramedic as defined in 105 CMR 170.000.

First Responder means a First Responder as defined in M.G.L. c. 111, §201 and 105 CMR 171.000, and who is authorized to administer controlled substances in accordance with 105 CMR 171.000, his or her training thereunder and the Statewide Treatment Protocols.

Statewide Treatment Protocols means the Emergency Medical Service Pre-Hospital Treatment Protocols approved by the Department for application statewide in accordance with M.G.L. c. 111C and 105 CMR 170.000.

700.003: Registration of Persons for a Specific Activity or Activities In Accordance With M.G.L. c. 94C, § 7(g)

700.003(A) – Delete in its entirety and insert the following:

(A)

- (1) An EMT-Paramedic, or an EMT-Paramedic student as part of his or her participation in a Department-approved Paramedic training program, may administer only those controlled substances, in quantity and kind, that are necessary for the performance of his or her duties;**
- (2) An EMT-Intermediate, EMT-Intermediate student as part of his or her participation in a Department-approved Intermediate training program, EMT-Basic or EFR may administer only those controlled substances in Schedule VI for which he or she has been approved by the Department and that are necessary for the performance of his or her duties;**
- (3) Administration of controlled substances by an EMT, EMT-Paramedic student, EMT-Intermediate student or EFR is also subject to the following conditions:**
 - (a) The ambulance service or EFR service for which the individual serves, shall be registered in accordance with 105 CMR 700.004 for the appropriate controlled substances;**
 - (b) The ambulance service or EFR service shall maintain a current listing of names of its employees and volunteers who are authorized to administer controlled substances;**
 - (c) The EMT, EMT-Paramedic student, EMT-Intermediate student or EFR shall perform only those functions for which he or she is authorized by, and trained in accordance with, 105 CMR 170.000;**
 - (d) Administration of controlled substances shall be conducted:**
 - 1. pursuant to the order of a practitioner and the Statewide Treatment Protocols; and**
 - 2. in accordance with 105 CMR 170.000 and the provisions of the Statewide Treatment Protocols.**

700.003(D) – Delete in its entirety and insert the following:

(D) Persons specified in 105 CMR 700.003(D) may administer epinephrine or atropine, pralidoxime chloride or other designated nerve agent antidotes in a life threatening emergency, where medical professionals are not readily available, in accordance with any applicable Department protocols and to the extent authorized by 105 CMR 700.003(D).

- (1) The following persons may administer epinephrine or nerve agent antidotes:**
 - (a) a first responder may administer epinephrine in accordance with 105 CMR 171.000 and the Statewide Treatment Protocols;**
 - (b) a public employee of or volunteer to a municipality or agency, department or authority of the Commonwealth (“agency”), whose function includes emergency preparedness and response and who is designated by a municipality’s or agency’s medical director pursuant to 105 CMR 700.003(6)(b) (“authorized public employee”), may administer epinephrine as well as atropine, pralidoxime chloride and other nerve agent antidotes approved by**

- the Department (“nerve agent antidotes”) to another authorized public employee; and
- (c) an authorized employee of or volunteer to a facility or program funded, operated or licensed by a municipality or agency may administer epinephrine to individuals served by such a program or facility (“program”);
- (2) A municipality or agency may approve administration of epinephrine or nerve agent antidotes by authorized public employees, and a municipality or agency may approve administration of epinephrine by employees or volunteers of a program, provided that the municipality or agency registers with the Department in accordance with 105 CMR 700.004. This registration requirement shall not apply to:
- (a) a municipality or agency registered under 105 CMR 700.004(A)(2)(a) through (A)(2)(t); or
- (b) a school district or non-public school subject to the provisions of 105 CMR 210.000;
- (3) Any administration is pursuant to the order of a practitioner, and, in the case of first responders, the Statewide Treatment Protocols;
- (4) The epinephrine or nerve agent antidote is:
- (a) dispensed by a pharmacy pursuant to the order or prescription of a practitioner or other authorized prescriber ; or
- (b) obtained by a municipality or agency in accordance with said entity’s registration;
- (5) The epinephrine or nerve agent antidote is packaged in a prefilled, automatic injection device intended for self-administration;
- (6) A qualified, licensed practitioner shall be designated by the registered municipality or agency as medical director for purposes of 105 CMR 700.003(D). Such person shall:
- (a) be the responsible person named on the registration of the municipality or agency;
- (b) authorize administration of epinephrine and nerve agent antidotes, as appropriate, and oversee compliance with 105 CMR 700.003(D);
- (c) establish and enforce written protocols and procedures to ensure that individuals administering epinephrine or nerve agent antidotes are properly trained, evaluated for competence, and up to date in their skills and knowledge. Training shall include, but not be limited to:
- (i) procedures for risk reduction;
- (ii) recognition of the symptoms of a severe allergic or nerve agent reaction;
- (iii) proper use of an auto-injector;
- (iv) procedures for notification of emergency medical services and other appropriate persons following administration;
- (d) establish and enforce written protocols and procedures to ensure:
- (i) proper storage, handling and return or disposal of epinephrine or nerve agent antidote;
- (ii) review and evaluation of an emergency response;
- (iii) reporting of adverse events to the medical director; and
- (iv) monitoring of program compliance with 105 CMR 700.003(D); and
- (e) establish and enforce written protocols and procedures to ensure that a registered municipality or agency, or a program if authorized to administer epinephrine by a municipality or agency, maintains current and readily retrievable records of:

- (i) the authorized public employees or volunteers who may administer epinephrine and nerve agent antidotes or authorized program employees or volunteers who may administer epinephrine;
 - (ii) individual trainings and evaluations;
 - (iii) receipt and any return or disposal of epinephrine or nerve agent antidotes; and
 - (iv) administration of epinephrine or nerve agent antidote;
- (7) Each program authorized by a registered municipality or agency to administer epinephrine pursuant to this section shall:
 - (a) comply with the policies and procedures established by the registered municipality or agency pursuant to 105 CMR 700.003(D);
 - (b) designate a licensed health care practitioner, whenever possible, or the program director or designee, to oversee the program's implementation of said policies and procedures;
 - (c) in the case of minors served by the program, obtain prior informed consent whenever possible from the minor's parent or legal guardian for the administration of epinephrine;
 - (d) develop individualized medication administration plans that address indications for administration of epinephrine, any unique issues around storage or handling of the epinephrine and persons to be notified in the event that epinephrine is administered; and
 - (e) immediately notify emergency medical services and designated contact persons, including those identified in the medication plan, in the event that epinephrine is administered; and
- (8) The registered municipality or agency, and the Department of Public Health, shall have full access to all pertinent records for monitoring purposes.

700.004: Registration Requirements

700.004(A)(2)(l) –Delete and insert the following:

(l) Ambulance Service/EFR Service

700.004(A)(2)(u) – Add the following:

(u) Municipality/Agency

700.004(C)(1)(g) – Delete in its entirety and insert the following:

(g) A registered ambulance service or EFR service shall only be registered to possess and administer those controlled substances and instruments used to administer controlled substances, in quantity and in kind, that are necessary for pre-hospital emergency medical care in accordance with 105 CMR 170.000 and the Statewide Treatment Protocols and that are obtained from the hospital pharmacy, provided that auto-injectors containing epinephrine, atropine, pralidoxime chloride or other antidotes and medications approved by the Department may be obtained directly from the manufacturer or another source registered by the Department.

700.004(C)(1)(j) – Add the following new section:

(j) A municipality or agency, department or authority of the Commonwealth is registered to possess and administer, in accordance with 105 CMR 700.003(D), epinephrine and nerve agent antidotes, which are dispensed by a pharmacy pursuant to the order of a practitioner, provided that epinephrine for use by first responders and nerve agent antidotes may be obtained directly from the manufacturer or another source registered by the Department.